

**Witness name: Ellen Kraig, Ph.D.**

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University of Texas Health Science Center, San Antonio, TX

*Dr. Kraig, who is the Chair of the Committee on Public Affairs of The American Association of Immunologists (AAI), will be testifying on behalf of AAI regarding the FY 2007 budget for the National Institutes of Health (NIH)*

**Hearing:** House Appropriations Subcommittee on Labor, Health and Human Services,  
Education and Related Agencies  
Hearing on the Fiscal Year 2007 budget  
Wednesday, March 29, 2006 at 2:00 p.m.

**Testimony summary:**

AAI represents more than 6,500 research scientists and physicians who are the world's leading experts on the immune system and who generally depend on NIH funding to support their work. Immunological research is crucial if we are to 1) prevent and treat diseases caused by natural infectious agents, including influenza and avian flu, SARS, tuberculosis, and AIDS, as well as those that may be modified for use as agents of bioterrorism, including plague, smallpox, and anthrax; and 2) prevent and treat chronic diseases, including cancer, autoimmune diseases, inflammatory disorders, and immunodeficiencies. Recent advances in immunology have led to the development of effective new treatments (including for rheumatoid arthritis, inflammatory diseases, and cancer) and vaccines (e.g., for Hemophilus influenza type b, dramatically reducing the incidence of pediatric meningitis in the U.S.). None of these advances could have been made without substantial public investment in basic immunological research.

AAI is very grateful to this subcommittee and the Congress for doubling the NIH budget. We are concerned, however, that the doubling has already been eroded as annual increases in the NIH budget have not kept pace with biomedical research inflation. Moreover, the President's FY 2007 "flat" budget would result in an effective decrease in the NIH budget, to devastating effect: 1) lower Institute paylines (even lower than the current and too low 10-14%); 2) no inflationary increases for direct, recurring costs in non-competing Research Project Grants; 3) damage to our ability to attract and retain the best young minds; and 4) threatening to the United States' preeminence in science in the face of aggressive competition from other nations.

AAI urges the subcommittee to increase the NIH budget by 5% (\$1.4 billion) in FY 2007, for a total budget of \$29.75 billion. This increase, which is only 1.2% above the projected rate of biomedical research inflation, would enable researchers to capitalize on important advances that have resulted from the doubling, including in pandemic influenza and biodefense research, and would assist efforts to attract and retain bright young scientists to research careers.

NIH should also use its funds as effectively as possible. To that end, AAI recommends that 1) funds allocated to the "NIH Roadmap for Medical Research" not grow faster than the overall NIH budget; and 2) NIH partner with not-for-profit scientific publishers to provide enhanced public access to NIH-funded research results, rather than continuing an expensive and duplicative effort to publish manuscripts itself.

**Testimony of Ellen Kraig, Ph.D., The American Association of Immunologists,  
before the House Appropriations Subcommittee on Labor, Health and Human Services,  
Education and Related Agencies, Regarding the FY 2007 Budget  
for the National Institutes of Health  
March 29, 2006**

Mr. Chairman, Mr. Obey, and members of the subcommittee: My name is Ellen Kraig and I am a professor in the Department of Cellular and Structural Biology at the University of Texas Health Science Center at San Antonio. I am here today in my capacity as chair of the Committee on Public Affairs of The American Association of Immunologists (“AAI”) to express our views on FY 2007 funding for the National Institutes of Health (NIH).

The AAI is a not-for profit professional society representing more than 6,500 research scientists and physicians who are the world’s leading experts on the immune system. While our members work in academia, government, and industry, most are among the more than 200,000 research personnel affiliated with more than 3,000 institutions who depend on NIH funding to support their work.<sup>1</sup> With approximately 84% of NIH funds awarded to these individuals and institutions, NIH’s funding level has a huge impact both on the advancement of biomedical research and on the local, state, and national economies.

**The importance of immunology**

Immunological research is crucial in a world increasingly at risk from infectious agents and chronic diseases.<sup>2</sup> Basic research on the immune system provides a foundation for the development of diagnostics, vaccines, and therapeutics. Current efforts are focused on preventing and treating diseases caused by natural infectious agents, including influenza and avian flu, SARS, West Nile Virus, tuberculosis, and AIDS, as well as those that may be modified for use as agents of bioterrorism, including plague, smallpox, and anthrax. In addition, basic immunological research continues to be crucial in the development of increasingly effective

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<sup>1</sup> National Institutes of Health FY 2007 Performance Budget Overview, pp.1-2. Many AAI members are medical school professors and researchers who receive grants from NIH, and in particular from the National Institute of Allergy and Infectious Diseases (NIAID) and the National Cancer Institute (NCI) (as well as other NIH Institutes and Centers), to support their research endeavors.

<sup>2</sup> Immunologists depend heavily on the use of animal models in their research. Without animal experimentation, theories about immune system function and treatments that might cure or prevent disease would have to be tested first on human subjects, something our society - and our scientists - would never countenance. Despite the clear necessity for animal research, we are experiencing both increasing regulatory burden in animal experimentation (eroding the return on NIH’s investment), and threats from people and organizations that oppose such research. The legal and illegal methods used by some groups to further an animal-rights/anti-medical research agenda are diverting precious resources from our work, threatening the personal safety and security of scientists, and delaying the progress of important research now underway.

approaches for treating chronic diseases, including cancer, autoimmune diseases, inflammatory disorders, and immunodeficiencies.

The immune system works by recognizing and attacking “foreign invaders” (i.e., bacteria and viruses) inside the body. It also plays an important role in controlling the growth of tumor cells. The immune system can protect its host (human or animal) from illness or disease either entirely - by attacking and destroying the virus, bacterium, or tumor cell - or partially, resulting in a less serious illness. But even a healthy immune system cannot completely protect us from all threats that might cause disease. Moreover, the immune system also has a “dark side”: it can lead to the rejection of transplanted organs or bone marrow and - if it is working improperly - can allow the body to attack itself instead of an invader, resulting in an “auto-immune” disease (e.g., Type 1 diabetes, multiple sclerosis, rheumatoid arthritis).

Recent advances in immunology have allowed for revolutionary treatments. For example, therapeutic substances called “biologics” have provided new, effective treatments for painful, debilitating and life-threatening diseases such as rheumatoid arthritis, inflammatory diseases, and cancer. Biologics that use modified human antibodies and cell receptors specifically target the substance (TNF) that causes joint destruction in rheumatoid arthritis, and the painful symptoms of psoriasis, and ankylosing spondylitis. An engineered antibody (herceptin) is being used to control the reoccurrence of breast cancer; resulting in a two-fold reduction in reoccurrence. Another monoclonal antibody and human protein - CTLA4Ig – has been dramatically effective in clinical trials treating prostate cancer and melanoma as well as showing promise as a treatment for lupus, arthritis, multiple sclerosis, and organ transplant rejection.

Immunologists have also focused on improved approaches to vaccine development, including a vaccine for *Hemophilus influenza* type b. This vaccine has reduced the incidence of pediatric meningitis in the U.S. from approximately 20,000 to 200 cases per year. Our understanding of what makes an efficacious vaccine will be critical as we face future pandemics, be they natural, like avian flu, or altered pathogens that could be used for bioterrorism, like missilized anthrax.

None of these advances could have been made without substantial public investment in basic immunological research. But even as we make huge strides, new threats emerge: immunologists are working feverishly to defend against bird flu and potential bioterrorism pathogens.

### **The NIH budget: trouble in the post-doubling years**

AAI is very grateful to this subcommittee and the Congress for doubling the NIH budget from FY 1998 to FY 2003. This “doubling” represented an unprecedented commitment by the federal government to preventing, treating, and curing disease, and has allowed scientists to begin new, cutting edge research made possible by recent advances in sequencing the genomes of humans, model organisms, and microbial pathogens that cause human and animal diseases.

But scientific research takes time, and the doubling of the NIH budget will have been for naught if we are unable to complete ongoing studies or retain trained personnel. Indeed, the doubling has already been eroded. Since 2003, the annual increases in the NIH budget have not kept pace

with biomedical research inflation.<sup>3</sup> Moreover, the President's FY 2007 "flat" budget would result in an effective decrease in the NIH budget, only the second time in 36 years that the NIH budget has been reduced. This would have a devastating effect:

1. Key NIH Institutes could be forced to drop paylines even lower than the current, far too low 10-14% (significantly below the approximately 22% funded during the doubling)<sup>4</sup>;
2. There would be no inflationary increases for direct, recurring costs in non-competing Research Project Grants (RPGs), undermining NIH's FY 2007 goal to "preserve to the greatest extent possible the ability of scientists to obtain individual support for their research ideas." National Institutes of Health Summary of the FY 2007 President's Budget February 6, 2006, p.3;
3. It would have rapid, adverse repercussions on the future of the research enterprise. Our brightest young people will be deterred from pursuing biomedical research careers if their chances of receiving an NIH grant become even lower. If we cannot attract and retain the best young minds, the United States will lose its preeminence in science and technology to nations - including India, Singapore, China, and Korea - that are investing aggressively to compete.
4. It would not permit increases in already inadequate stipends to pre- and post-doctoral fellows, and will undermine efforts to attract excellent scientists to NIH and to academia.

### **Pandemic Influenza/Influenza**

Influenza leads to more than 200,000 hospitalizations and about 36,000 deaths nationwide in an average year. Pandemic influenza could cause millions of deaths and hospitalizations. Despite these very real threats, the President's FY 2007 NIH Budget includes an increase of only \$17 million to support specific research initiatives focused on pandemic influenza, bringing total NIH spending on influenza to approximately \$199 million (about \$35 million over FY 2006).

The vast majority of funds (more than \$3 billion) appropriated to date under the Department of Health and Human Services Pandemic Influenza Preparedness Plan have been devoted to other pandemic influenza related activities (including production/procurement of vaccines/antivirals). While these public health efforts are extremely important, it is essential to realize that any existing pathogen that could cause influenza or pandemic influenza (e.g., bird flu) can mutate, rendering existing countermeasures ineffective. Since new influenza strains can quickly emerge, research to identify new pathogens, understand the immune response, and develop tools for

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<sup>3</sup> NIH funding increases/decreases since the doubling period ended [FY 2004 (3.03%), FY 2005 (2.18%) and FY 2006 (-.12%)] have all been below the "Biomedical Research and Development Price Index ("BRDPI"), a U.S. Department of Commerce ("DOC") estimate of the cost of inflation for biomedical research. The BRDPI was developed by the DOC's Bureau of Economic Analysis under an agreement with NIH and is updated annually. It indicates how much the NIH budget must increase to maintain purchasing power. Projections for future years are prepared by the NIH Office of Science Policy.

<sup>4</sup> AAI analyzed paylines of key NIH Institutes from FY 2000 – FY 2002; see [www.nih.gov](http://www.nih.gov).

protecting against the pathogen should never take a back seat to other pandemic influenza-related activities. The need for this research supports AAI's request for an increased budget for NIH.

### **Biodefense research**

AAI supports the President's request for \$1.891 billion for biodefense research, an increase of 6.2% over FY 2006. NIH's FY 2007 biodefense research priorities include continuing work on developing vaccines and treatments for anthrax, smallpox, plague, tularemia, hemorrhagic fevers, and botulinum toxin.

NIH plans to direct \$160 million to an Advanced Development Fund ("ADF") within the Office of the NIH Director to "support efforts to work with academia and industry to develop candidate countermeasures from the point of Investigation New Drug Application (INDA) to the level that these candidate countermeasures could be eligible for acquisition by Project Bioshield." AAI urges that the NIH Director work closely with the NIAID Director to ensure that the ADF focuses on NIH's traditional expertise in basic and translational research and not on activities relevant to commercial development or the manufacturing of a product.

NIH also plans to spend \$25 million to construct additional high containment laboratories at biosafety level (BSL) 3 and to renovate existing labs to meet current BSL-3 standards. (BSL-3 labs are necessary for the safe conduct of research on dangerous and infectious pathogens.) AAI recommends that these funds be used first for the renovation of existing labs; the construction of new labs may not be necessary with the limited research funding that may be available this year.

### **Administrative Issues**

#### *1. Office of Portfolio Analysis and Strategic Initiatives*

AAI supports the newly formed Office of Portfolio Analysis and Strategic Initiatives (OPASI) as a way of better managing and analyzing NIH's portfolio. While we understand the need for a "Common Fund" to support OPASI, we believe that, in this difficult fiscal climate, such a fund should be limited and should grow no faster than the overall NIH budget.

#### *2. Research, Management and Support (RM&S)*

The President's FY 2007 budget proposal for Research, Management and Services (RM&S), which supports the management, monitoring, and oversight of intramural and extramural research activities (including NIH's highly regarded peer review process), includes an increase of \$14 million, or 1.3%. AAI supports an appropriate increase in the RM&S budget to ensure that it is sufficient 1) to enable NIH to supervise a portfolio of increasing size and complexity and 2) to ensure that NIH funds are well and properly spent.

#### *3. Outsourcing*

AAI continues to be concerned about the "outsourcing" of NIH jobs. While certain NIH jobs may be appropriate for such an approach, it should not be applied to program administration staff, many of whom are highly experienced and have historical knowledge and understanding of NIH programs and policies. Such outsourcing would result in the loss of a dedicated and capable workforce and reduce efficiency in the long run.

## **AAI's recommended budget increase for FY 2007: 5% (1.2% above projected inflation)**

AAI strongly believes that we must increase the NIH budget now in order to capitalize on important advances that have resulted from the doubling. We urge this subcommittee to increase the NIH budget by 5% (\$1.4 billion) in FY 2007, for a total budget of \$29.75 billion. This increase, which is only 1.2% above the projected rate of biomedical research inflation, would enable researchers to capitalize on important advances that have resulted from the doubling, leading to increased translational and clinical applications. It would also assist efforts to attract and retain bright young American scientists to research careers.

## **The effective use of NIH funds**

While AAI advocates a 5% increase in NIH funding, we agree that NIH should use its existing funds as effectively as possible. To that end, we recommend the following:

### **1) The "NIH Roadmap for Biomedical Research" ("NIH Roadmap")**

AAI notes that the President's FY 2007 budget request for the NIH Roadmap has grown to \$443 million, an increase of \$113 million over FY 2006. While AAI supports this effort to fund multidisciplinary, interdisciplinary research and agrees that such research is an important part of biomedical research in the 21<sup>st</sup> century, we recommend that funds allocated to the NIH Roadmap not grow faster than the overall NIH budget and that all Roadmap funds, including the Director's Pioneer Awards, be awarded through a rigorous peer review process.

### **2) NIH "Enhanced Access to Scientific Publications" Policy**

AAI recommends that NIH partner with not-for-profit scientific publishers to provide enhanced public access to NIH-funded research results, rather than continuing an expensive effort to publish manuscripts itself. In this era of limited funds, NIH should work with these willing partners to ensure that its budget is used to support and advance research and not to duplicate services already provided by the private sector. AAI urges the subcommittee to support efforts underway between NIH and the not-for-profit scientific publishing community to develop a policy that will enhance public access while addressing the concerns of publishers.

### **3) Peer review and the independence of science**

Millions of lives – as well as the prudent use of taxpayer dollars - depend on government officials receiving – and taking - the very best and most independent scientific advice available. We urge this subcommittee to provide oversight which ensures that funds expended enhance the ability of scientists to provide independent scientific advice (particularly on government scientific advisory panels) and preserve independent peer review (including ensuring the review of scientific research results by peers through robust, independent scientific journals).

## **Conclusion**

AAI greatly appreciates this opportunity to testify and thanks the members of this subcommittee for your strong support for biomedical research, the NIH, and the scientists who devote their lives to preventing, treating, and curing disease. We look forward to working with you and hope that you will contact me or AAI if you have any questions or if we can be of assistance.

Ellen Kraig submits this document pursuant to House Rule XI, Clause 2(g).

## **Curriculum Vitae for ELLEN KRAIG**

### **EDUCATION:**

University of Denver, Denver, CO      B.S. in Biology, 1975  
Brandeis University, Waltham, MA      Ph.D. in Biology, 1980  
California Institute of Technology, Pasadena, CA      Post-doctoral fellow in Molecular Immunology 1980-1983

### **ACADEMIC POSITIONS:**

1983-1991      Assistant Professor, Department of Cellular and Structural Biology, UTHSCSA  
1991-1997      Associate Professor, Department of Cellular and Structural Biology, UTHSCSA  
1992-present      Member, San Antonio Cancer Institute  
1997-04;1989-93      Chair, Graduate Program in Cellular and Structural Biology  
1997-present      Professor, Department of Cellular and Structural Biology, UTHSCSA

### **PROFESSIONAL ACTIVITIES:**

2005-2009      Member, NIH Vaccines Against Microbial Diseases Study Section (VMD)  
2005-2006      Chair, AAI Public Affairs Committee (Committee member since 2000)  
2005-present      Science Advisory Board, Texans for the Advancement of Medical Science  
2005      Adhoc Member, NIH Oral, Dental and Craniofacial Sciences Study Section  
2004-2007      Council for the Asilomar Midwinter Immunology Conference, elected member  
2003      NIH Special Panel on Myasthenia gravis (IMS subcommittee)  
2002-2003      NIDCR Special Grants Review Committee  
2000-2005      AAI Representative to the FASEB Science Policy Committee  
2000-2003      Elected to the University Senate, UTHSCSA  
2001-2005      Associate Editor, Mechanisms of Aging and Development  
1996-2000      Member NIH Immunological Sciences Study Section (IMS)  
1988-2006      Recombinant DNA Safety Committee, SFBR  
1989-1993      Member, NIH Transplantation Biology and Immunology Study Section (TBIS)  
1994      Adhoc Member, NIH Oral Biology and Medicine I Study Section (OBMI)  
1994      Adhoc Member, NIH Allergy and Immunology Study Section (ALY)  
1994-1999      Associate Editor, *The Journal of Immunology*  
1996-1999      Research Allocations Advisory Committee, American Heart Association, Texas Affiliate

### **HONORS AND AWARDS:**

1975      Phi Beta Kappa and University of Denver Biology Department Chairman's Award  
1996      UTHSCSA Presidential Award for Teaching Excellence  
2000      Dean's Award for Excellence in Graduate Teaching



The American Association of Immunologists, Inc. (“AAI”) submits this document pursuant to House Rule XI, Clause 2(g).

AAI received the following Federal grants (or sub-grants thereof) or contract (or subcontracts thereof) during the current fiscal year or either of the two previous fiscal years:

*1. From the National Institutes of Health (NIH)/National Institute of Allergy and Infectious Diseases (NIAID):*

*Grant No. 5 R25 AI043872*

*Grant Title: Teaching Biology Through Immunology Fellowships*

Notice of Grant Award for the period February 1, 2005 – January 31, 2006: \$68,500 authorized

Received during AAI’s current fiscal year (calendar 2006): \$0

Received during AAI’s prior fiscal year (calendar 2005) on a cash basis: \$54,166.73; on an accrual basis, \$52,866.00

Received during AAI’s 2<sup>nd</sup> prior fiscal year (calendar 2004) on a cash basis: \$156,260.20\*; on an accrual basis, \$65,576.61.

\* This amount is high because we needed to delay requesting payment until all the reconciliations of prior grants and draws to date had been completed.

*2. From the National Institutes of Health Minority Access to Research Careers (MARC) Program:*

AAI does not receive funds directly from this program, though some of our trainee members (or faculty) did receive grants. In 2004, AAI received \$1,112.65 reimbursement for room and program costs.